DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
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December 19, 2014

PorOsteon, Incorporated
% BioVera, Incorporated
Robert A. Poggie, PhD
100 Promenade Saint Louis
Notre-Dame-de-L'Ile-Perrot, Quebec, J7V 7P2
Canada

Re: K142041
Trade/Device Name: PorOsteon Phusion Metal Cervical Cage
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: ODP
Dated: November 21, 2014
Received: November 25, 2014

Dear Dr. Poggie:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K142041

Device Name

PorOsteon Phusion Metal Cervical Cage

Indications for Use *(Describe)*

The Phusion Metal Cervical Cage is indicated for intervertebral body fusion of the spine in skeletally mature patients. The Phusion Metal Cervical Cage is intended for use at one level in the cervical spine, from C3 to C7, for the treatment of cervical disc disease (defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies). The Phusion Metal Cervical Cage is to be used in patients who have had six weeks of non-operative treatment. Devices are intended to be implanted via an open, anterior approach and used with autogenous bone and supplemental fixation, such as an anterior plating system.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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Department of Health and Human Services
Food and Drug Administration
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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) SUMMARY

PorOsteon, Inc. – Phusion Metal Cervical Cage

In accordance with 21 CFR 807.92 of the Federal Code of Regulations, the following information is a summary of safety and effectiveness PorOsteon's Phusion Metal Cervical Cage device.

A. SUBMITTERS INFORMATION

Submitter Name:	BioVera, Inc.
Submitter Address:	65 Promenade Saint-Louis, Notre-Dame-De-L'Ile-Perrot, Quebec, J7V 7P2, CANADA
Contact Person:	Robert A Poggie, PhD
Phone Number:	(514) 901-0796; (973) 738-6097
Fax Number:	(514) 901-0796
Date of Submission:	July 22, 2014

B. DEVICE IDENTIFICATION & MANUFACTURER

Manufacturer Name:	PorOsteon, Inc.
Manufacturer Address:	605 Cambridge Ave. Suite B Menlo Park, CA 94025 USA
Registration Number:	TBD
Contact Name:	Robert (Bob) Zider
Title:	President & CEO
Device Trade Name:	PorOsteon Phusion Metal Cervical Cage
Device Common Name:	Intervertebral body fusion device
Classification Name:	Intervertebral body fusion device - cervical
Classification Code:	ODP – Class II
Classification Panel:	Orthopedic
Regulation Number:	21 CFR section 888.3080

C. PREDICATE DEVICES

K103033	Trabecular Metal Fusion Device; manufactured by Zimmer Trabecular Metal Technology, Inc.

D. DEVICE DESCRIPTION

The Phusion Metal Cervical Cage is an intervertebral fusion device intended to act as a disc spacer and hold bone graft to promote fusion in the cervical spine. The Phusion Metal Cervical Cage is anatomically shaped with two holes in the anterior end of the device each having a diameter of two millimeters extending to the inner cavity. The Phusion Metal Cervical Cage is manufactured from a porous titanium-nickel (Ti-Ni) intermetallic material. The Phusion Metal Cervical Cage is offered in a variety of shapes and sizes to accommodate variations in patient anatomy. The superior and inferior surfaces of the device has a pattern of teeth to provide increased stability and inhibit movement of the implants. Phusion Metal Cage implants are available in one lordotic configuration of 7°and heights ranging from 5 to 10 mm in 1 mm increments. The Phusion Metal Cage device is single-use only.

Materials: Porous titanium-nickel (Ti-Ni) intermetallic material.

E. INTENDED USE

The Phusion Metal Cervical Cage is indicated for intervertebral body fusion of the spine in skeletally mature patients. The Phusion Metal Cervical Cage is intended for use at one level in the cervical spine, from C3 to C7, for the treatment of cervical disc disease (defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies). The Phusion Metal Cervical Cage is to be used in patients who have had six weeks of non-operative treatment. Devices are intended to be implanted via an open, anterior approach and used with autogenous bone and supplemental fixation, such as an anterior plating system.

F. TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE

The subject Phusion Metal Cervical Cage devices are machined from porous Titanium-Nickel intermetallic bar stock, and are intended for permanent implantation in the cervical spine. Phusion Metal Cervical Cage devices are designed to fit the anatomic profile of the cervical spine. Two size options (depth x width) are available, 12.5 x 14.5 mm and 14.5 x 16.5 mm. All devices are designed with seven (7) degrees of lordosis and are available in height options ranging between 5 and 10 mm in 1 mm increments.

The technological characteristics of PorOsteon Phusion Metal devices are the same as the cited predicate device excepting a change in the porous metal material used to machine the devices and slight variations in geometry. The subject PorOsteon Phusion Metal Cervical Cage devices are machined from porous Titanium-Nickel intermetallic material with nominal porosity of 63% and compressive elastic modulus of 1.0 GPa. The predicate Zimmer Trabecular Metal Fusion devices are machined from porous tantalum material. Both the predicate and subject devices are manufactured from porous metal materials and are indicated for use as an interbody spacer in the cervical spine. The technological characteristics of the PorOsteon Phusion Metal Cervical Cage devices are substantially equivalent to the cited predicate device.

G. PERFORMANCE DATA

Characterization of Phusion Metal Cervical Cage devices was performed per the FDA Guidance Document entitled “Class II Special Controls Guidance Document: Intervertebral Body Fusion Device” issued on June 12, 2007. Biomechanical evaluation of the devices was performed per ASTM standards F2077-11, F2267-04, F1714-96, and draft standard F-04.25.02.02. Static and dynamic compressive, shear, and torsion strength of the worst-case devices were measured per ASTM F2077-11. The subsidence characteristics of the worst case device were measured per ASTM F2267-04. Static expulsion testing of the worst-case device for the Phusion Metal Cage and a competitive PEEK device were measured and compared per ASTM draft standard F-04.25.02.02. Collection and characterization of wear debris from dynamic testing was characterized per applicable sections of ASTM F1714-96.

Biocompatibility testing of the porous Ti-Ni intermetallic material was performed per ISO 10993 standards.

Bone apposition, ingrowth, spinal fusion, large organs, blood, and serum were evaluated in an ovine model of lumbar spinal fusion of 2 non-contiguous levels (L2-L3 and L4-L5; n = 8 sheep), and sacrifice time points of 4 and 6 months. Blood analysis and serum biochemistry were performed pre-operatively, post-operatively, and weekly up to 6 weeks and monthly thereafter (N=88 total blood samples) through 6 months. The study was performed with commercially available control devices of similar design fabricated from Zeniva PEEK material; both the control and subject devices were implanted with autograft bone harvested from the iliac crest. The ovine study was performed per Good Laboratory Practices (GLP) by the Preclinical Surgical Research Laboratory, Colorado State University, USA.

The results of the biomechanical tests showed to Phusion Metal Cages to meet or exceed the strength requirements for cervical spinal devices, and to possess subsidence and expulsion characteristics typical of spinal fusion devices fabricated from permanent polymer or metallic materials. ISO 10993 biocompatibility testing showed the porous Ti-Ni intermetallic Phusion Metal material to be biocompatible and elicit no adverse reactions. Histology, micro-CT, in-life radiography and CT, and biomechanical evaluation of Phusion Metal Cervical Cage devices in the ovine model showed no evidence of adverse tissue reaction, no evidence of migration or pseudoarthrosis, normal bone and soft tissue at the fusion sites, 100% rate of fusion at 6 months (4 sheep, 2 devices/sheep), statistically equivalent fusion at 6 months to the control devices based on bone histology and biomechanical motion, and a statistically significant, higher percentage of bone contact of the superior and inferior surfaces of the devices at 4 and 6 months for the Phusion Metal devices as compared to the PEEK control devices (23.90% vs. 9.94% at 4 months and 56.09% vs. 27.31% at 6 months). Histopathology of the major organs, blood work, ICP-MS of blood, and serum biochemistry showed normal levels of nickel (Ni) with respect to the control PEEK devices and the scientific literature; there was no evidence of abnormal nickel levels for all tissue, blood, and serum samples evaluated in the ovine study.

H. CONCLUSION

The PorOsteon Phusion Metal Cervical Cage system is substantially equivalent to the predicate device, the Zimmer Trabecular Metal Fusion Device.